Section 9 - SUMMARY OF SAFETY AND EFFECTIVENESS

OCT 1 2 2001

K013229

510(k) Summary

Ferrania, July 27, 2001

Ferrania S.p.A.
Viale della Libertà 57
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Savona (Italy)

Contact: Ing. Mannella Paolo
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Device:

Trade name:	LifeRay™ FW Mammo Cassette LifeRay™ KW Mammo Cassette
Common Name:	Radiographic film cassette for mammography
Classification Name:	Radiographic film cassette (per 21 CFR 892.1850)
Medical specialty	Radiology
Product code	IXA
Predicate Device:	Kodak MIN-R 2 CASSETTE (510(k) number: K890361), Kodak Corp., 343 State Street, Rochester, NY 14650 0207.

Description and Intended Use of Device

Ferrania LifeRay™ Mammo Cassettes are intended for use during mammography diagnostic procedures to hold radiographic film in close contact with an x-ray intensifying screen and to provide a light proof enclosure for direct exposure of this film. The Cassettes are available in two sizes and two models. The LifeRay™ KW Mammo Cassettes contain a window that is compatible with Kodak ID Printers for marking film with patient identification data. The LifeRay™ FW Mammo Cassettes contain a window that is compatible with Ferrania ID Printers for the same purpose as before.

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Technological Characteristics

Both Ferrania LifeRay™ Mammo Cassettes and the predicate device are composed of:

- a light tight chamber for preventing radiographic film exposure,
- a compressible backplate material to assure intimate film-screen contact,
- a latching mechanism for removal and replacement of radiographic film.

Performance data

Voluntary standards to which the Ferrania LifeRay™ Mammo Cassettes conform are:

- ANSI PH1.49 – 1995[2]
- ISO/FDIS 4090: 2000.

Conclusion

Based on the analysis of the comparison made between the LifeRay™ Mammo Cassettes and the predicate device, Ferrania S.p.A. concluded that the LifeRay™ Mammo Cassettes are safe, effective and perform as well as the predicate device.

[2] CDRH Recognized Consensus Standard

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 2 2001

Ferrania S.P.A.
% Ms. Chantel Carson
Engineering Team Leader
Underwriters Laboratories Inc.
333 Pfingsten Road
NORTHBROOK IL 60062-2096

Re: K013229
Trade/Device Name: LifeRay™ FW Mammo Cassette
LifeRay™ KW Mammo Cassette
Regulation Number: 21 CFR 892.1850
Regulation Name: Radiographic film cassette
Regulatory Class: II
Product Code: 90 IXA
Dated: September 25, 2001
Received: September 27, 2001

Dear Ms. Carson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known) K013229

Device Name: **LifeRay™ FW Mammo Cassette**
LifeRay™ KW Mammo Cassette

Indications for Use:

Ferrania LifeRay™ Mammo Cassettes are intended for use during mammography diagnostic procedures to provide a light-proof enclosure for direct exposure of X-ray films and to hold the film in close contact with an X-ray intensifying screen.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use _____

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013229